



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

October 9, 2021

MEMORANDUM

Subject: Efficacy Review for SurfaceWise 2 Antimicrobial Surface Coating
EPA File No. 92082-E;

From: Tajah Blackburn, Ph.D.
Senior Scientist
Efficacy Branch (EB)
Antimicrobials Division (7510P)

Thru: Kristen Willis, Ph.D., Chief
Efficacy Branch
Antimicrobials Division (7510P) *Kristen Willis*
Date Signed: 10/13/2021

To: Jack Hall, Risk Manager/Eric Miederhoff, PM31
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Allied BioScience, Inc.
7500 Dallas Pkwy, Suite #800.
Plano, TX 75024

Formulation from the Label (Dated 8/10/2021):

Active Ingredients	% by wt.
1-Octadecanaminum, N, N-dimethyl -N[3-(trihydroxysilyl) propyl], chloride	0.75%
Other Ingredients:	99.25%
Total	100.00%

I. BACKGROUND

Product Description (as packaged, as applied): Ready-to-Use Liquid.

Submission type: New end use product

Currently registered efficacy claim(s): N/A

Requested action(s): Register as non-food contact sanitizer and microbiostat

Documents considered in this review:

- Cover Letter, dated 5/7/2021
- EPA Form 8570-4, Confidential Statement of Formula, dated 2/18/2021
- EPA Form 8570-27, Formulator's Exemption Statement, dated 2/18/2021
- EPA Form 8570-35, Data Matrix, dated 2/18/2021
- EPA Form 8570-1, Application for Pesticide, dated 2/18/2021
- Efficacy studies
 - MRID No. 51475512 and *Klebsiella pneumoniae*, dated 5/6/2021 (No MRID number, ASTM E1153-14: Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces (Modified for Spray Application))
 - MRID No. 51652001 was submitted as an addendum to MRID 51475512 in response to the technical screen
- Proposed Label, (dated 8/10/2021)
- Document Flairosol versus Electrostatic Sprayer (undated)

Note: Studies to support residual claims will not be reviewed in this action as communicated to the registrant in the technical screen failure. A revised Data Matrix was not submitted to reflect removal of residual studies and addition of *Klebsiella pneumoniae*.

II. PROPOSED DIRECTIONS FOR USE

Users must be trained in the application of SurfaceWise2 prior to use.

For Sanitization

Electrostatic Sprayer

Spray surfaces from a distance of about 12-60 inches to the point of saturation (actual distance may vary depending on the manufacturer and model of electrostatic sprayer being used, consult the manufacturer's user's manual prior to use), being careful not to let the liquid start to drip or bead up. A sheen will be present on the surface when complete. Allow surfaces to remain wet for at least 5-minutes. Allow surfaces to air dry, or if desired, wipe with clean [disposable] [microfiber] cloth. Surfaces should be visibly dry and/or dry to the touch before handling.

Manual Sprayer

Spray surfaces from a distance of about 6-8 inches to the point of saturation, being careful not to let the liquid start to drip or bead up. To ensure complete protection, spray from all angles to

ensure all surfaces of the object are covered. A sheen will be present on the surface when complete. Allow surfaces to remain wet for at least 5- minutes. Allow surfaces to air dry, or if desired, wipe with clean [disposable] [microfiber] cloth. Surfaces should be visibly dry and/or dry to the touch before handling.

For Use as A Microbiostatic Agent

Prior to application of SurfaceWise2, surfaces must be pre-cleaned with a low residue cleaner, to eliminate visible dirt or grease spots. This will ensure effective binding of the coating to the surface.

Electrostatic Sprayer

Spray surfaces from a distance of about 12-60 inches to the point of saturation (actual distance may vary depending on the manufacturer and model of electrostatic sprayer being used, consult the manufacturer's user's manual prior to use), being careful not to let the liquid start to drip or bead up. A sheen will be present on the surface when complete. Allow surfaces to air dry. Surfaces should be visibly dry and/or dry to the touch before handling.

Manual Spray Application

Spray surfaces from a distance of about 6-8 inches to the point of saturation, being careful not to let the liquid start to drip or bead up. To ensure complete protection, spray from all angles to ensure all surfaces of the object are covered. A sheen will be present on the surface when complete. Allow surfaces to air dry. Surfaces should be visibly dry and/or dry to the touch before handling

III. STUDY SUMMARIES

1.	MRID	51475512	Study Completion Date:		December 9, 2020		
Study Objective/Title		ASTM E1153-14: Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces (Modified for Spray Application)					
Testing Lab / Lab Study ID		Allied Bioscience Protocol Number: ABS-M002					
Test organism(s) <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Staphylococcus aureus (ATCC 6538), Pseudomonas aeruginosa (ATCC 15442)					
Test Method		ASTM E153-14 Modified for Spray Application (copy provided)					
Application Method		Flairosol sprayer from a distance of 6-8 inches					
Test Substance Preparation	Name/ID	SurfaceWise2					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	112001-LCL, 112002-LCL, and 112003-LCL					
	Preparation	Ready to use liquid test substance was applied using a Flairosol sprayer					
Soil load		5% Fetal bovine serum (FBS)					
Carrier type, # per lot		1 in ² glass carriers/5 carriers per organism and per lot					
Test conditions		Contact time	5 minutes ± 5 seconds	Temp	22 ±1°C	RH	45-50%
Neutralizer		Dey-Engley Broth					
Reviewer comments		Carriers were inoculated with 0.01 mL of test culture for both organisms with organic soil load. Carriers were then dried at 36.9°C					

(i.e., protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	at 42% RH for 38 minutes for <i>S. aureus</i> and 37 minutes for <i>P. aeruginosa</i> . The geometric mean of control carriers for <i>P. aeruginosa</i> was 6.32×10^5 (ASTM requirement: 7.5×10^5) thus not meeting the study criteria. The registrant argued that all test carriers were at the limit of detection ($\leq 1.0 \times 10^1$), and that the conclusion from this study is not expected to change if the control carrier met the acceptance criteria. The method of application (3 sprays every 30 seconds for 5 minutes) appeared inconsistent with the required method of application. An addendum to the study (MRID No. 51652001) clarified the method of application.
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2.	MRID	No number	Study Completion Date:		May 6, 2021		
Study Objective/Title		ASTM E1153-14: Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces (Modified for Spray Application)					
Testing Lab / Lab Study ID		Allied Bioscience Protocol Number: ABS-M002					
Test organism(s) <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Klebsiella aerogenes (ATCC 13048)					
Test Method		ASTM E153-14 Modified for Spray Application (copy provided)					
Application Method		Flairosol sprayer from a distance of 6-8 inches					
Test Substance Preparation	Name/ID	SurfaceWise2					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	112001-LCL, 112002-LCL, and 112003-LCL					
	Preparation	Ready to use liquid test substance was applied using a Flairosol sprayer					
Soil load		5% Fetal bovine serum (FBS)					
Carrier type, # per lot		1 in ² glass carriers/5 carriers per organism and per lot					
Test conditions		Contact time	5 minutes ± 5 seconds	Temp	22 ±1°C	RH	45-50%
Neutralizer		Dey-Engley Broth					
Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Carriers were inoculated with 0.01 mL of test culture for both organisms with organic soil load. Carriers were then dried at 36.9°C at 35% RH for 35 minutes. The geometric mean of control carriers for <i>K. aerogenes</i> was 7.35 x 10 ⁵ (ASTM requirement: 7.5 x 10 ⁵) thus not meeting the study criteria. The registrant previously argued that all test carriers were at the limit of detection (≤1.0 x 10 ¹), and that the conclusion from this study is not expected to change if the control carrier met the acceptance criteria.					

V. RESULTS

MRID Number	Organism	Results (CFU/mL)			Log ₁₀ Reduction
		Lots	Survivors	Control	
			Geometric Mean		Percent Reduction
514755-12	<i>Staphylococcus aureus</i> (ATCC 6538)	112001-LCL	$<1.45 \times 10^1$	1.11×10^6	≥ 99.9987
		112002-LCL	$<3.5 \times 10^1$		99.9968
		112003-LCL	$<2.9 \times 10^1$		99.9974
	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	112001-LCL	≤ 1.00	6.32×10^5	≥ 99.9984
		112002-LCL	≤ 1.00		≥ 99.9984
		112003-LCL	≤ 1.00		≥ 99.9984
		112001-LCL	≤ 1.00	7.35×10^5	≥ 99.9986

No Number Provided	<i>Klebsiella aerogenes</i> (ATCC 13048)	112002-LCL	≤1.00		≥99.9986
		112003-LCL	≤1.00		≥99.9986

VI. CONCLUSIONS

MRID	Claim	Surface Types	Application Method(s) and Dilution	Contact Time	Soil load	Organism(s)	Data support tested conditions?
514755-12	Non-Food Contact Sanitization	Hard Non-Porous	RTU	5 minutes	5%	<i>Staphylococcus aureus</i> (ATCC 6538) <i>Pseudomonas aeruginosa</i> (ATCC 15442)	Yes
No MRID Number Provided	Non-Food Contact Sanitization	Hard Non-Porous	RTU	5 minutes	5%	<i>Klebsiella aerogenes</i> (ATCC 13048)	Yes

Notes:

1. Spray distance was 6-8 inches with 3 sprays applied for coverage.
2. [Wetness testing consistent with MLB SOP MB 31 and a video to demonstrate the surface remains wet for the duration of the contact time with electrostatics spray applications.](#)

VII. LABEL COMMENTS

Proposed Label dated August 10, 2021

1. The proposed label claims are acceptable regarding the product, SurfaceWise2 (EPA File No. 92082-E), as a non-food contact sanitizer in the presence of organic soil for a contact time of 5 minutes when applied with a Flairosol sprayer at the ready-to-use preparation against qualifying bacteria *Staphylococcus aureus* (ATCC 13048), *Klebsiella aerogenes* (ATCC 13048) and additional bacterium *Pseudomonas aeruginosa* (ATCC 15442).
 - a. The spray distance specified in the study report of 6-8 inches in the test system does not support the spray distance of 12-60 inches specified for electrostatic spray applications on the proposed label. The label should be revised to specify a spray distance of 6-8 inches consistent with the efficacy data.
 - b. In addition, please address the following on the proposed label for electrostatic applications consistent with the [Agency instructions for adding electrostatic spray directions for use](#):
 - Spray droplet particles size (regardless of the ability to change nozzles that impact particle size) limited to a volume media diameter (VMD) ≥ 40 µm.
 - Instructions to place the electrostatic spray function in the ON position for electrostatic spray models that have the functionality to toggle ON/OFF
2. The proposed label claims that the product, SurfaceWise2 (EPA File No. 92082-E), is a microbiostatic agent (targeting non-public bacteria, fungi (mold/mildew), and algae) on non-food contact, non-porous surfaces for a period up to 90 days. Non-public health microbiostatic claims are acceptable however the 90-day timeframe should be removed or supported by efficacy data.
3. Please make the following additional changes to the proposed label:

- On page 2,
 - Remove the claim “Protected by SurfaceWise2”. Claims that imply protection from disease are not permitted. See Chapter 12 of EPA’s [Label Review Manual](#)
 - Remove the following claims as these claims are not limited to microbiostatic uses and are listed in the general label claims:
 - “Protected Surface Barrier”
 - “Persistent”
 - “Formulated for comfort”
 - “Leaves an invisible coating, barrier, or protectant”
 - “Always-On”
 - “Non-disruptive”
 - “The invisible layer of protection”
 - Include “non-porous” in the following claim
 - “Compatible across a broad range of surfaces”.
 - “broad surface use”
- On page 3,
 - Revise the claim “Can reduce the spread of illness-causing bacteria on [non-porous surfaces]” to “Can help reduce the risk of cross-contamination from treated surfaces”.
 - Revise the claim “[Kills] [eliminates] [destroys] [removes] [reduces] 99.9% of bacteria on commonly touched surfaces that can be transfer points for bacteria [on] [:] [insert use sites on Table 1]” to “[Kills] [eliminates] [destroys] [removes] [reduces] 99.9% bacteria on commonly treated commonly touched surfaces that can be transfer points for bacteria [on] [:] [insert use sites on Table 1]”
 - Revise the claim “Controls the [spread] [transmission] of [bacteria] on [non-porous surfaces] [insert surfaces from Table 2]” to “Controls the [spread] [transmission] of bacteria on treated [non-porous surfaces] [insert surfaces from Table 2]”
 - Revise the claim “Can help reduce the risk of cross-contamination” to “Can help reduce the risk of cross-contamination from treated surfaces”
- For the following microbiostatic claims, add “non-public” or “odor causing” as accurate descriptors for all bacteria, fungi (mold and mildew), and algae claims
 - On page 4, remove patient rooms and veterinary facilities use locations for microbiostatic claims
 - On page 5, change “porcelain” to “glazed porcelain”.
 - On page 5, change vinyl to “non-porous” vinyl.